No. 23-55645

In the United States Court of Appeals

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, EX REL. 3729, LLC,

Plaintiff - Appellant,

v.

EVERNORTH HEALTH, INC.; EXPRESS SCRIPTS, INC.,

Defendants - Appellees.

On Appeal from the United States District Court for the Southern District of California, No. 19-cv-1199 (Robinson, J.)

APPELLEES' ANSWERING BRIEF

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CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1, Appellees Evernorth Health, Inc., and Express Scripts, Inc. make the following disclosures:

- **Express Scripts, Inc.** is a wholly owned subsidiary of Evernorth Health, Inc.
- **Evernorth Health, Inc.** is a wholly owned subsidiary of The Cigna Group (f/k/a Cigna Corporation).
- The Cigna Group is a publicly held company that indirectly owns more than ten percent (10%) of Express Scripts, Inc. and Evernorth Health, Inc.'s stock.
- The Cigna Group has no parent corporation, and no publicly held corporation owns ten percent (10%) or more of its stock.

Dated: January 16, 2024

s/ Eric W. Sitarchuk
ERIC W. SITARCHUK

Counsel for Evernorth Health, Inc., and Express Scripts, Inc.

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INTRODUCTION

This is the prototypical parasitic lawsuit the False Claims Act ("FCA")'s public disclosure bar seeks to eliminate. Relator 3729, LLC is a shell company (named after the FCA, 31 U.S.C. § 3729) that was formed in June 2019 solely to bring this suit. The Complaint alleged a single fraud: that Defendant Express Scripts, Inc. ("ESI") over-dispensed prescriptions to Tricare beneficiaries by auto-refilling 90-day supplies of medication every 60 days. But this was publicly reported years before Relator filed suit. This inconvenient fact alone dooms the Complaint.

In 2013, the *Army Times*, a publication widely read throughout the defense community, published an article claiming ESI over-dispensed medication to Tricare beneficiaries by sending refills too often, ***specifically*** by shipping 90-day supplies every 60 days. Further, the Federal Register, through a Department of Defense ("DoD") notice-and-comment rulemaking spanning 2015 to 2016, publicly disclosed auto-refilling policies for Tricare prescriptions that allegedly resulted in unnecessary waste. Both disclosures occurred before the Complaint was filed.

Try as it might, Relator cannot distinguish the core fraud it alleges from what was made public years earlier—that ESI over-dispensed medicine by shipping 90 pills every 60 days. Settled Ninth Circuit law requires application of the public-disclosure bar on these facts. Further, Relator is not an original source. Relator's background information and ancillary details do not permit an end run around the

bar. Nor could Relator have direct or independent knowledge of the alleged conduct, which occurred before Relator even existed.

The Complaint fails to state a claim under the FCA for additional reasons, each of which requires dismissal and provides an alternative basis for affirmance. The Complaint fails to allege falsity because it does not identify any regulatory or contractual standard for the timing of refills—let alone one that ESI violated. The Complaint also fails to adequately allege materiality and scienter. Nothing in the Complaint shows that the supposed "fraud" would affect the government's decision to pay ESI for its services. To the contrary, public documents incorporated in the Complaint reveal the government knew about the frequency of ESI's refills and paid those claims anyway: proof positive that the "fraud" was not material, and that ESI did not have the requisite scienter to "lie" to the government.

This Court should affirm the dismissal of Relator's Complaint.

STATEMENT OF THE ISSUES

1. Whether the district court correctly held that the FCA's public-disclosure bar precludes Relator's Complaint.

2. Whether dismissal should be affirmed for the alternative reason that the Complaint fails to state a claim.

STATEMENT OF THE CASE

I. Background[1]

A. The Parties

Defendant ESI is a wholly owned subsidiary of Defendant Express Scripts Holding Company ("ESHC"), which was formed after the 2012 merger of ESI with Medco Health Solutions ("Medco").[2] *See* 1-ER-004. ESI is a large pharmacy benefit manager, providing pharmacy services to over 85 million people nationwide. *Id.* (citing Compl. ¶8). "ESI also operates retail, mail-order, and specialty pharmacies, including the Tricare mail-order pharmacy located in Tempe, Arizona." *Id.* (quoting Compl. ¶8).[3]

"Tricare provides health insurance benefits, including prescription drug coverage, to approximately 9.4 million eligible beneficiaries around the world, including active[-]duty service members, retirees, and their family members and dependents." 1-ER-003 (quoting Compl. ¶22). "Since October 1, 2013, Tricare has been managed by the Defense Health Agency [('DHA')] within [the Department of Defense ('DoD')]." *Id.* (quoting Compl. ¶23).

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[1] As the district court did (1-ER-003 n.2), Defendants accept as true Relator's well-pleaded allegations only for purposes of this motion-to-dismiss appeal.

[2] ESHC is now known as Evernorth Health, Inc.

[3] This brief refers to Defendants collectively as ESI, including because the Complaint plainly states no claim against ESHC. *See* 3-ER-245.

"Beginning in 2003, ESI contracted with the DoD 'to provide critical pharmacy services, including mail-order delivery of prescription drugs, to uniformed service members and their families enrolled in Tricare, the U.S. military's comprehensive health insurance program.'" 1-ER-004 (quoting Compl. ¶¶1, 24, 34). "ESI 'has dispensed hundreds of millions of prescriptions pursuant to these contracts'" with DoD. *Id.* (quoting Compl. ¶24).

Relator 3729, LLC was created on May 29, 2019, less than a month before filing this lawsuit on June 26, 2019, and after all the alleged conduct in this case occurred. 1-ER-028; *see* 3-ER-284; 3-ER-339; 3-ER-372. One of Relator's principals "was the Pharmacist-in-Charge ('PIC') of ESI's Tempe, Arizona mail-order pharmacy where Tricare prescriptions are processed." 1-ER-004. This former-PIC is ***not*** a relator in this case, 3-ER-338, despite the Complaint and Relator's appellate brief erroneously referring to the former-PIC as "the Relator PIC" or "the PIC Relator." *See, e.g.*, 3-ER-348 (Compl. ¶31); 3-ER-354-57 (Compl. ¶¶54, 56); 3-ER-362 (Compl. ¶88-89); Relator Br. 21, 52.

According to the Complaint, the former-PIC was employed by ESI in Tempe "from October 2009 until March 2018," where "he ha[d] first-hand knowledge of how [ESI's] mail-order pharmacy program operated" and "raised concerns [but not to the government] about the excessive medication dispensed on auto-refill." 1-ER-004 (citing Compl. ¶¶7, 56, 88-89). "Relator's other [unidentified] principals are

senior executives of a[n] [unnamed] technology company and have [unspecified] first-hand knowledge of [ESI's] member experiences,[4] dispensing, and business practices." *Id.* (quoting Compl. ¶7).

B. Allegations in the Complaint

Relator alleges that from October 2009 until early 2018, ESI: (i) enrolled "as many Tricare beneficiaries as possible in automatic delivery" and (ii) "calibrat[ed] the logic of [ESI's] pharmacy dispensing software so that a full days-supply of each maintenance prescription was automatically dispensed at the 67% usage date (*e.g.*, 60 days on a 90-day supply), with the refill 'clock' immediately reset after each refill for the life of a prescription." 1-ER-004-05 (quoting Compl. ¶3; citing *id.* ¶¶34-42, 44-45, 53, 60, 63-68, 72-73). "According to Relator, 'this auto-refill pattern caused an excess of 265 pills—an extra nine-month supply—to be dispensed for each prescription over the course of a year … generating enormous piles of drug waste.'" 1-ER-005 (quoting Compl. ¶3, citing *id.* ¶44).

Relator claims ESI knew this practice resulted "in a rapidly growing quantity of unused and unneeded medication," leading to complaints from beneficiaries and unused expired medication. 1-ER-006 (citing Compl. ¶¶43, 49-52, 60, 91-93). The Complaint also alleges that ESI's refill practices led to Tricare bearing "unnecessary

[4] By definition, this would be second-hand knowledge of ESI's practices.

costs in the form of extra dispensing fees, claims processing fees, and purchases of additional drugs." 1-ER-007 (quoting Compl. ¶45).

The Complaint alleges that ESI "hid its conduct from DoD and Tricare" by: (i) concealing the excessive dispensing "from the DoD during an audit performed by the DoD Inspector General in 2013/14" and (ii) inadequately responding to "concerns" raised by the DoD in 2015 about seven beneficiaries who "received excessive quantities of maintenance prescription medications." 1-ER-007.

The Complaint also alleges that ESI "changed its auto-refill practices to avoid detection" in "late 2017 or early 2018." *Id.* (quoting Compl. ¶¶110, 114).

Relator claims that the above-described conduct failed to "adhere to the Tricare Provider Manual, which requires" compliance "with all Tricare program regulations, policies, and procedures." 1-ER-008 (quoting Compl. ¶28). Relator alleges ESI violated the Tricare regulations defining fraud as including "claims which involve flagrant and persistent overutilization of services without proper regard for results, the patient's ailments, condition, medical needs, or the physician's orders." 32 C.F.R. § 199.9(c)(5); *see* 3-ER-347 (Compl. ¶¶26-27); 3-ER-349 (Compl. ¶35); 3-ER-352 (Compl. ¶46); 3-ER-355 (Compl. ¶58); 3-ER-358-59 (Compl. ¶¶69, 74). Likewise, Relator alleges violations of several state regulations requiring that drug dispensation is "consistent with prescription order," has a legal

quantity and "frequency of refills," and otherwise does not allow the "over-utilization of drugs." 1-ER-008-09 (citing Compl. ¶¶30-33, 61-62, 75).

C. Public Disclosures

In December 2013, the *Army Times* published an article entitled: *DoD: Mail-order meds program may waste money*. That article reads, in relevant part:

> A Pentagon report says the contractor that manages Tricare's pharmacy benefit may be ***wasting money by continuing to ship drugs to beneficiaries who no longer need them or dispensing 90-day, instead of 30-day, prescriptions***.
>
> The report by the Defense Department Inspector General found that Tricare's Mail Order Pharmacy program costs the government and beneficiaries less money than retail stores. But the IG also noted it had no data on how much medicine is wasted by the program, managed by Express Scripts.
>
> The National Community Pharmacy Association says that information is needed to know whether the home delivery system saves money. And ***beneficiaries with up to a year's worth of drugs piled in medicine cabinets and linen closets*** are wondering, as well.
>
> "***They ship 90-day supplies after 60 days. By the time I get 12 months into this, I have a nine-month supply of drugs.*** And I don't dare stop the medications because they'll never get it started again," said retired Air Force Master Sgt. Wayne Stanfield, 70, of South Boston, Va.
>
> …
>
> The IG found that between April and June 2012, TMOP saved the Pentagon nearly 17 percent over Tricare's retail pharmacy option: $399 million versus nearly $466 million at retail stores, according to the Pentagon.

But the analysis did not include such items as contract costs and administrative overhead associated with mail order or retail prescriptions—or data on waste.

Stanfield received four prescriptions by mail, and his wife receives 10. They reluctantly switched to mail order in 2012 when their copayments through retail pharmacies increased to $5 for generics and $12 for brand names.

At first, the refills ran smoothly, Stanfield said. But in early 2013, Express Scripts changed its website customer interface and made it "nearly impossible to reach the company," he said. Emails arrive in his inbox informing him a prescription needs to be renewed, but don't specify the drug's name or the beneficiary. Phone messages are left on his voice mail, also without any names or specific details.

"Why is there this push to make it mandatory when the program is broken? Somebody needs to look at Express Scripts. ***They are making a fortune off the government, and there are a tremendous amount of retirees who are getting chewed up by the system***," Stanfield said.

…

According to the Pentagon, Tricare for Life beneficiaries make up 22 percent of the Tricare population but account for 53 percent of Tricare's yearly pharmacy costs. Public Health Service Rear Adm. Thomas McGinnis, Tricare's pharmacy chief, said the mandatory mail order policy could save DoD at least $200 million a year.

Retirees, however, continue to question the math and the program. Retired Navy Chief Petty Officer Donald Shafer, of Wasilla, Alaska, said he sometimes receives notices that Express Scripts is out of stock of his medicine.

"I'm forced to purchase the drugs locally at a much higher price," Shafer said. "What happens when Express Scripts is the only option? I agree long-term maintenance drugs can be obtained through Express Scripts, but only after they get their act together."

A 2012 survey by the Military Officers Association of America found that 75 percent of respondents—active or retired troops or family

> members—said they tried Tricare's home delivery. Of those, 92 percent said they were "mostly or very satisfied."
>
> …

3-ER-282 (emphases added).

Two years later, on August 6, 2015, the DoD issued an interim final rule to "require eligible covered [Tricare] beneficiaries generally to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail-order pharmacy program." *See* 80 Fed. Reg. 46,796-01, 46,796 (Aug. 6, 2015) (to be codified at 32 C.F.R. Part 199). In an official comment to the proposed rule, a "professional association commented with a number of concerns," including "***unnecessary waste resulting from auto-ship policies*** and the suggestion to implement policies ***to ensure mail order refills are approved and needed***." 81 Fed. Reg. 76,307-01, 76,309 (Nov. 2, 2016) (to be codified at 32 C.F.R. Part 199) (emphases added).[5] The DoD, in adopting the final rule, specifically responded to this comment that it believed "the current statutory requirement of Section 702" of the 2015 National Defense Authorization Act "requiring eligible covered beneficiaries generally to refill non-generic prescription maintenance medications

[5] Both the interim final rule and the final rule cited in this paragraph are entitled: "Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Refills of Maintenance Medications Through Military Treatment Facility Pharmacies or National Mail Order Pharmacy Program."

through military treatment facility pharmacies or the national mail order program … is being implemented successfully and without adverse effects on beneficiaries." *Id.*

II. Procedural History

Relator filed its Complaint on June 26, 2019. 3-ER-338-73. The United States declined to intervene on June 16, 2022, after which the Complaint was unsealed and served on ESI. 1-ER-009.

ESI timely filed a motion to dismiss. 3-ER-211-48. It moved to dismiss under the FCA's public-disclosure bar—which precludes *qui tam* FCA lawsuits "if substantially the same allegations or transactions" have already been publicly disclosed in a qualifying public source and the Relator is not an "original source." 31 U.S.C. § 3730(e)(4); *see* 3-ER-225-37. ESI also moved to dismiss for failure to state a claim, arguing that Relator had not adequately alleged falsity, materiality, or scienter—three independent requirements under the FCA. 3-ER-237-46.

After supplemental briefing on the public-disclosure bar, 2-ER-101-30, a hearing on April 27, 2023, 2-ER-060-99, and supplemental briefs on recent public-disclosure cases within the Ninth Circuit, 2-ER-042-59, the district court issued its decision dismissing the Complaint without prejudice under the public-disclosure bar on June 16, 2023. 1-ER-002-33. The district court did not reach ESI's arguments regarding Relator's failure to state a claim. *See* 1-ER-033.

The district court reasoned that the 2013 *Army Times* article stating that ESI was shipping 90 days' worth of pills every 60 days and the 2015-2016 DoD Rulemaking accusations of waste through auto-refilling of medication publicly disclosed the information at the core of the fraudulent scheme Relator later alleged in the Complaint. 1-ER-012-25. The district court further held that, under both the 1986 and 2010 FCA public-disclosure bar definitions, Relator did not qualify as an "original source" because it lacked "direct knowledge" of the alleged fraud, 1-ER-026-28, and its allegations did not "materially add" to information the government already knew, 1-ER-029-32.

The district court dismissed the case without prejudice and allowed Relator 21 days to file an amended complaint. 1-ER-033. Relator declined to do so, and instead filed a motion requesting the court issue a final, appealable order. 2-ER-038. This appeal followed, 3-ER-389-90, and the district court dismissed the case with prejudice on September 21, 2023 to provide finality for the appeal. 1-ER-034-36.

SUMMARY OF ARGUMENT

I. The public-disclosure bar warrants dismissal of Relator's Complaint. Its core allegation that ESI's auto-refill policy led to excessive medicine being shipped to beneficiaries by shipping 90 pills every 60 days was already publicly disclosed. Under binding Ninth Circuit law, including *United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565 (9th Cir. 2016), a public source discloses substantially the same

fraudulent transaction when it discloses the same fraud's core elements. *Id.* at 571. The *Army Times* article and DoD notice-and-comment disclosed more than enough to satisfy this standard—and the additional background information and details alleged by Relator cannot defeat substantial similarity.

Relator is not an original source under either the 1986 or 2010 versions of the FCA public disclosure bar. Its claims fail under the 1986 bar because 3729, LLC has no "direct" (or firsthand) knowledge of the fraud. Its claims fail under both the 1986 and 2010 bars because it has no "independent" knowledge, or knowledge predating the public disclosures. Indeed, 3729, LLC was created well after the alleged conduct, and it is legally distinct from its members.

Relator also is not an original source under the 2010 bar because the Complaint's allegations do not materially add to what the government knew. Instead, the Complaint contains nothing more than additional color and some details, while the prior public disclosures had already put the government well on notice of the alleged fraud. Settled precedent is clear that this is insufficient to qualify as an original source.

II. Additionally, the Complaint fails to state an FCA violation. First, it fails to allege falsity because it cites no contractual or regulatory requirement or standard that ESI's purported dispensing practices violated. Second, it fails to allege materiality because it cites no misrepresentation that would have impacted the

government's payment decisions, especially given the government's continued payment of claims after learning of ESI's alleged conduct. Third, it fails to allege that ESI possessed the requisite scienter given the government had knowledge of and approved the purportedly false claims.

STANDARD OF REVIEW

This Court reviews "a district court's ruling on a motion to dismiss a FCA action *de novo*." *United States v. Allergan, Inc.*, 46 F.4th 991, 996 (9th Cir. 2022).

Under Federal Rule of Civil Procedure 12(b)(6), a complaint must allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* And, as Relator concedes (at 26 n.2), an FCA complaint must satisfy the heightened pleading standard of Rule 9(b) and plead fraud with specificity. *See Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010).

ARGUMENT

I. The FCA's Public-Disclosure Bar Forecloses the Complaint.

A complaint must be dismissed under the public-disclosure bar if (as relevant here): (1) there was a prior "public disclosure" of substantially similar allegations or transactions of the fraud alleged in the Complaint, and (2) the relator fails to qualify

as an "original source" within the meaning of the statute. *See United States ex rel. Calva v. Impac Secured Assets Corp.*, 2018 WL 6016152, at *3 (C.D. Cal. 2018).

This two-step inquiry applies under both the 1986 and 2010 versions of the FCA's public-disclosure bar—though the analysis at the original-source stage varies to some degree between them. Because courts apply the version of the FCA in effect at the time the claim at issue was submitted, *see Bloedow v. Planned Parenthood of the Great Nw. Inc.*, 2013 WL 6631771, at *2 (W.D. Wash. 2013), *aff'd*, 654 F. App'x 335 (9th Cir. 2016), and because the Complaint alleges conduct from October 2009 to early 2018 (though not alleging when claims were submitted), both versions of the public-disclosure bar apply in this case.

For claims submitted before March 23, 2010 (which are a small minority, if any, of the claims), the 1986 bar applies. It provides: "No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions … in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation[;] or from the news media, unless … the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A) (1986). It defines "original source" as "an individual who has direct and independent knowledge of the information on which the allegations are based." *Id.* § 3730(e)(4)(B).

The rest of the claims are governed by the 2010 public-disclosure bar. It instructs courts to dismiss "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed … (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless … the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A) (2010). An original source is an individual who voluntarily disclosed to the government the information underlying the complaint before the public disclosure—indisputably not applicable here—***or*** "who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." *Id.* § 3730(e)(4)(B).

The essential fraudulent transactions alleged in Relator's Complaint are the same as those publicly disclosed in two public sources before the Complaint was filed: a 2013 *Army Times* article and DoD's 2015-2016 notice-and-comment rulemaking regarding Tricare's Mail Order Pharmacy ("TMOP") program. The district court was correct to hold these public sources disclosed substantially the same alleged fraudulent transactions as the Complaint and that Relator is not an original source of the information.

A. Substantially the Same Transactions Raised in the Complaint Were Publicly Disclosed in the News Media and the Federal Register.

Both the 1986 and 2010 bars require a "public" disclosure "through one of the channels specified in the statute" and that Relator's action is "substantially the same

as the allegation or transaction publicly disclosed." *Allergan, Inc.*, 46 F.4th at 996; *United States ex rel. Solis v. Millennium Pharms., Inc.*, 885 F.3d 623, 626 (9th Cir. 2018). Here, Relator concedes that the two public-disclosure sources relied on by the district court—the *Army Times* article and the DoD final rulemaking Federal Register comments—are "public" through qualifying "channels specified in the statute." *See* 1-ER-018; 2-ER-140 n.3; Relator Br. 28 ("there is no dispute" the sources are public "channels").[6]

Thus, the only dispute is whether the *Army Times* article and DoD final rulemaking comments are "substantially similar" to the allegations in Relator's Complaint.[7] They are.

The substantial similarity standard does not require public disclosures and a complaint to be identical, let alone to contain the same details. Rather, public disclosures and a complaint are substantially similar "when the prior public disclosure put the government 'on notice to investigate the fraud before the relator

[6] Relator also does not dispute that the district court was correct to consider these materials as judicially noticeable. *See* 1-ER-013 n.5 (citing, *e.g.*, *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018)).

[7] Under the 1986 statute, the relator's claims must be "based upon" the public disclosure, but the Ninth Circuit long interpreted that phrase to mean substantially the same or substantially similar, so the 2010 change in language did not change the standard. *See Silbersher v. Valeant Pharms. Int'l, Inc.*, – F.4th –, 2024 WL 58386, at *9 (9th Cir. 2024) ("Congress re-enacted its prior law in clearer terms … leaving our precedent interpreting that phrase undisturbed.").

filed his complaint.'" *Solis*, 885 F.3d at 626; *United States v. N. Am. Health Care, Inc.*, 173 F. Supp. 3d 943, 949 (N.D. Cal. 2016) (bar applies "if the public disclosure 'was sufficient to enable [the government] adequately to investigate the case'" (alteration in original)); *see also Amphastar Pharms. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 703 (9th Cir. 2017) (only a "critical mass of the underlying facts or of the allegations" must be disclosed). A public source discloses substantially the same "allegation or transaction" of fraud if it makes "a direct claim of fraud" or refers "to facts from which [substantially similar] fraud can be inferred." *Mateski*, 816 F.3d at 570-71.

The district court was right to hold that the 2013 *Army Times* article and the DoD notice-and-comment rulemaking procedure in 2016 "disclosed the allegedly fraudulent transactions at issue." 1-ER-020; *see* 1-ER-019-25. Both include facts disclosing substantially the same fraudulent transactions as the Complaint: over-dispensing medication, including auto-refilling 90 days of medication every 60 days.

The *Army Times* article specifically discloses that ESI dispensed "90-day, instead of 30-day, prescriptions," after only "60 days." 3-ER-282. It goes on to claim that TMOP beneficiaries had "up to a year's worth of drugs piled in medicine cabinets and linen closets." *Id.* As a result, according to the article, "12 months into" their prescriptions, participants had an extra "nine-month supply of drugs." *Id.* As the article explained, these claims were publicized further by the National

Community Pharmacists Association ("NCPA"), a lobbying group for retail pharmacies that competed directly with TMOP for service member customers.[8] *Id.* The article alleged that ESI was "making a fortune off the government" through this purported scheme. *Id.*

The Complaint's core allegation of fraud rests on precisely the same conduct the *Army Times* article described: that ESI sent 90-day refills of medication every 60 days, allegedly causing beneficiaries to receive an excessive amount of medication. *See* 3-ER-339-40 (Compl. ¶3); 3-ER-350-51 (Compl. ¶¶37-40). Relator alleges that, as a result, "[a]fter one year, a beneficiary had received and still had on-hand, including the first fill, 265 pills, *i.e.*, almost nine months of extra medication" that they were "storing in [their] medicine cabinet," in words nearly identical to the article. 3-ER-352 (Compl. ¶44); *see* 3-ER-339-40 (Compl. ¶3); 3-ER-350 (Compl. ¶¶38-39). Indeed, on appeal, Relator cannot help but describe its core fraud claim the same way: "ESI set its auto-refill program to refill prescriptions *every 60 days on 90-day prescriptions*," leading to "excess dispensing fees and unnecessary drug resupplies." Relator Br. 1-2 (emphasis in original).

Both the *Army Times* article and the Complaint identify the same key aspects of the alleged fraudulent scheme: (1) ESI automatically provided patients with 90-

[8] *See* National Community Pharmacists Association, https://ncpa.org/ (last visited Dec. 26, 2023).

day supplies of medication after 60 days; and (2) as a result, patients received nine months of extra medication within a year and accumulated unneeded medicine. This mirroring more than establishes substantial similarity.

Here, the alleged fraudulent transactions in the Complaint and *Army Times* are not merely "similar in kind," which was sufficient to satisfy the Ninth Circuit in *Solis*, 885 F.3d at 627, but they are the same. The *Army Times* article revealed "the exact type of fraudulent conduct" the Complaint alleges, *N. Am. Health Care*, 173 F. Supp. 3d at 949—*i.e.*, filling 90-day refills every 60 days. As the district court held, "the same actors, the same conduct, and the same risk," along with the same "core" fraudulent transaction, "were involved in both the prior disclosure and relator's complaint." 1-ER-024-25 (citing *Solis*, 885 F.3d at 626; *United States ex rel. Sam Jones Co. LLC v. Biotronik Inc.*, 2023 WL 2993409, at *7 (C.D. Cal. 2023), *appeal pending*).

Thus, the degree of similarity here exceeds what is necessary under the "substantial similarity test," which, as Relator concedes, requires only that the disclosure and complaint be "similar in kind, even if slightly less so in degree." *Solis*, 885 F.3d at 627 ("The prior disclosure 'need not be identical with' [the] allegations to bar [relator's] claims." (quoting *Mateski*, 816 F.3d at 573)); *see id.* (rejecting argument that "claims are not substantially similar" because the relator provided "139 more pages of detail"); Relator Br. 38 (noting the district court

"[c]orrectly summariz[ed] the standard"). *See also United States ex rel. Jahr v. Tetra Tech EC, Inc.*, 2022 WL 2317268, at *9-10 (N.D. Cal. 2022) (bar applicable where news articles and complaint contained allegations that defendants did not screen or test transported dirt for radiation); *Amphastar*, 856 F.3d at 704 (bar applicable where disclosure and complaint "made nearly identical allegations" that defendant obtained patent and profited based on misrepresentations); *N. Am. Health Care*, 173 F. Supp. 3d at 949 (bar applicable where news article "publicly disclosed the exact type of fraudulent conduct, upcoding by providing unneeded therapy services, on which [the relator] rests his current upcoding FCA allegations").

As the district court reasoned, the "*Army Times* article is similar to the *New York Times* article that the district court concluded triggered the public-disclosure bar in *Sam Jones*." 1-ER-021; *see Sam Jones*, 2023 WL 2993409, at *1. In that case, a *New York Times* article noted the DOJ was investigating the defendant's sales and marketing products, and the article stated a "possible explanation" for the defendant's "market share increase" was developing relationships with doctors, including through "fraudulent nepotistic hiring and compensation practices" like "the hiring of a physician's family member." *Id.* at *6-7. Those disclosures were "sufficient [for the government] to infer fraud," and were substantially similar to allegations in the complaint because the article revealed the defendant "likely engaged in unlawful nepotistic hiring practices to increase device sales (alleged true

facts), while publicly claiming that its sales success was based on better products and proper relationships with doctors (alleged misrepresented facts)." *Id.* at *7. That was so even though the complaint provided additional details not included in the article such as "how many devices were implanted" by the doctor named in the complaint and "the specific names of other physicians involved in the alleged fraud." *Id.* at *8. All the court required was that "both the article and the [complaint] involve [the same] main actor and set-out the same core charge." *Id.* at *7-8. The same is true here with respect to the *Army Times* article, which set out the core charge of over-dispensing 90 pills every 60 days against the same main actor, ESI.

Relator claims (at 40-41) that the "specific tactic" was not revealed here, but it was: sending 90-day refills every 60 days.[9] Relator also argues that the allegations in the Complaint are more sweeping in "scope" and more explicitly involve "systematic[]" or "widespread" over-filling than the *Army Times* article did. Relator Br. 30-34; *see id.* at 19. As an initial matter, the law does not require anything close to the level of detail or scope in the public disclosure that Relator demands. The "disclosed allegation" does not "need to contain every specific detail to constitute disclosure." *Amphastar*, 856 F.3d at 704. Only a "critical mass of the underlying facts or of the allegations" must be disclosed. *Id.* at 703. Put differently, core factual

[9] Relator cites *Jahr* (at 40-41), but that case supports dismissal. It ruled that the bar applied because, as here, the disclosures revealed transactions like those in the complaint. 2022 WL 2317268, at *9-10.

overlap is all the bar requires. *Solis*, 885 F.3d at 626-27 ("differences in [] focus and framing" do not change that the "degree of overlap is sufficient to show substantial similarity"); *United States ex rel. Rahimi v. Rite Aid Corp.*, 3 F.4th 813, 826 (6th Cir. 2021) ("a single news article about a single investigation" triggered the bar because complaint related to "same scheme by the same corporate actor").

Relatedly, Relator insists (at 30-31, 38-39) that the *Army Times* article dealt with only one individual's experience, but that is not so. The district court correctly rejected this argument: "Despite Relator's attempts to narrow the scope of the *Army Times* article to a single instance of over dispensing prescription medication, the article opens with the findings of a July 2013 DoD IG report" discussing "wasting money by continuing to ship drugs to ***beneficiaries*** who no longer need them" and discusses "***beneficiaries*** with up to a year's worth of drugs piled in medicine cabinets and linen closets" and then offers an example of a beneficiary and his wife with "fourteen prescriptions" in their household who get "90-day supplies after 60 days" leading to an excess "nine-month supply of drugs" in a year. 1-ER-020-21 (emphases added).

Further, the article critiques ESI's filling practices in broad, systemic terms, relying on IG reports, an NCPA investigation, and multiple beneficiaries' testimonials, and notes DoD is missing data on "contract costs and administrative

overhead" and "waste." *See* 1-ER-021 (discussing 3-ER-282).[10] The article also alleges that ESI is "making a fortune off the government" and that "a tremendous amount of retirees … are getting chewed up by the system." 3-ER-282. These are all broad claims—not limited to one person. And that is confirmed by the NCPA lobbying group's involvement in the article, which would make little sense if it involved an alleged issue with just one patient. *See id.*

And, in any event, that ESI's purported scheme was allegedly occurring on a widespread scale "is an obvious inference based on the publicly disclosed allegations" and does not preclude application of the bar. *Amphastar*, 856 F.3d at 704. The quotes from an individual in the article reported as an illustrative example actually provide more specificity than the Complaint does and negate any suggestion that the disclosure is the kind of "generalized fraud" identified in *Mateski*. Taken as a whole, the article clearly discloses abuse of the auto-refill program to fill excessive scripts, and specifically identifies filling 90 pills every 60 days.

The *Army Times* article amply put the government "on notice to investigate the fraud before the relator filed [its] complaint." *Mateski*, 816 F.3d at 574. Thus, it publicly disclosed substantially the same fraudulent transaction alleged in the Complaint.

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[10] Relator also claims the article is "contradictory" because it noted ESI had been "out of stock" of some medicines, Relator Br. 33, but there is nothing contradictory between that allegation and ESI allegedly over-filling prescriptions when in stock.

The DoD final rulemaking comments focused on the alleged unnecessary waste emanating from auto-refilling, as also alleged in the Complaint. This prior disclosure occurred in the Federal Register during the DoD's notice-and-comment rulemaking procedure in November 2016. 1-ER-020-21. The Federal Register entry came after the *Army Times* article, which had already notified the government of the alleged filling of 90 pills every 60 days, and the DoD notice-and-comment added to that knowledge.

In particular, in response to a DoD interim final rule describing the process of providing 90-day refills to Tricare beneficiaries, a "professional association" commented about alleged "unnecessary waste resulting from auto-ship policies" and suggested implementing "policies to ensure mail order refills are approved and needed." 81 Fed. Reg. at 76,309. The "association" also argued that "beneficiaries should have to consent to getting a refill rather than automatic shipping." *Id.*

Both the rulemaking process and the Complaint refer to waste resulting from excessive, automatic 90-day shipments of medication sent without express authorization. *See id.* at 76,308-09; 3-ER-350-52 (Compl. ¶¶ 36-45).

These comments were not only made public, but were read and considered by DoD, the agency with ultimate oversight for TMOP. *See* 81 Fed. Reg. at 76,309 (noting DoD reviewed comments in response to interim final rule, including comment regarding "unnecessary waste resulting from auto-ship policies"); *see also*

Solis, 885 F.3d at 627 (finding bar applicable where disclosure revealed same fraudulent transactions even though in less detail than the complaint); *N. Am. Health Care*, 173 F. Supp. 3d at 949 (finding bar applicable where disclosures revealed "the exact type of fraudulent conduct" alleged in complaint).

And while the comments do not specifically name ESI, they discuss TMOP. Here, the class of potential wrongdoers is a class of one, because ESI was the exclusive contractor for TMOP. "The Ninth Circuit has recognized that the prior disclosure need not specifically name the FCA defendant so long as the class of potential wrongdoers is sufficiently narrow that it can be tied to a relatively specific allegation of wrongdoing." *United States ex rel. Lee v. Corinthian Colls.*, 2013 WL 12114015, at *6 (C.D. Cal. 2013).

Thus, the DoD rulemaking also revealed the underlying allegedly fraudulent transactions—*i.e.*, that ESI auto-shipped excessive medications that were not approved or needed. This rulemaking further put the government on the trail to investigate ESI's allegedly excessive refill policies.

In its brief (at page 29 and following), Relator focuses on *Mateski*'s formula for determining whether a public disclosure includes a "transaction" including the "material elements of the allegedly fraudulent transaction." 816 F.3d at 571. But that case does not help Relator. Rather, it confirms that "[t]he substance of the disclosure … need not contain an explicit allegation of 'fraud,' so long as" it contains

the "material elements" of the core fraudulent transaction alleged in the Complaint. *Id.* (quoting *United States ex rel. Found. Aiding Elderly v. Horizon W.*, 265 F.3d 1011, 1014 (9th Cir. 2001)). The *Mateski* Court went on:

> [I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. … [T]he combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed.

Id. X and Y are the two essential elements of: "a misrepresented state of facts and a true set of facts." *Id.*

As the district court found, this framework further supports the sufficiency of the disclosure here. It confirms the *Army Times* article and Federal Register need ***not*** make a direct claim (or "explicit 'allegation'") of fraud, *id.*, contrary to Relator's claim. *Contrast* Relator Br. 33-34 (implying public disclosure must include that the defendant "knowingly" engaged in actions through "deliberate efforts"); *id.* at 39 (citing out-of-circuit case for that proposition[11]), *with Solis*, 885 F.3d at 627 ("The absence of any explicit allegation of wrongdoing in the prior public disclosure 'is simply of no moment' so long as 'the material transactions giving rise to the

[11] *United States ex rel. Baltazar v. Warden*, 635 F.3d 866 (7th Cir. 2011), is inapplicable for the additional reason that the public reports in that case simply alleged chiropractic-industry fraud generally and never identified the ***defendant*** as "among the perpetrators of [the] fraud." *Id.* at 867-68. Here, the *Army Times* article clearly names ESI and it cannot be seriously disputed that the DoD rulemaking referred to any actor other than ESI because, as noted, ESI was the only Tricare pharmacy benefit manager (and thus the only one possibly being referred to in the DoD rulemaking).

[defendant's] allegedly unlawful … schemes were publicly disclosed.'") (quoting *A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000)).

In other words, contrary to Relator's argument, the public disclosure does ***not*** need to disclose the elements of an FCA claim, it needs to disclose the elements of the alleged fraud. *Mateski*, 816 F.3d at 571 ("the allegation of fraud and X and Y represent ***its*** essential elements") (emphasis added). Adding a requirement that the public disclosure describe the defendant's fraudulent intent would eviscerate the statutory language "allegations ***or transactions***," 31 U.S.C. § 3730(e)(4)(A) (emphasis added), and contradict Ninth Circuit case law.

Moreover, the *Army Times* article and Federal Register clearly reveal both "X" and "Y"—the true state of facts (ESI was dispensing wasteful quantities of unneeded medication) and the allegedly misrepresented state of facts (that DOD was nonetheless paying for the medication pursuant to the TMOP program). The article went further and described the precise methodology: that ESI allegedly dispensed 90 days of medication every 60 days pursuant to its auto-refill policies, rather than 90 days of medication every 90 days, which allowed the government to infer the "fraud" of purportedly excessive over-dispensing of medication.

Relator claims to add additional "pieces of the puzzle," including specifying the scope of the scheme, "ESI's specific intent," and methods to perpetuate the scheme including "software algorithms." Relator Br. 34. But none of those is

required to disclose the "transaction" from which fraud may be inferred. *Mateski*, 816 F.3d at 571. Relator cites *Silbersher*, but in that case, which this Court has revised since Relator filed its brief, the Court reiterated that the "formula" requires only X and Y such that "fraud can reasonably be inferred." 2024 WL 58386, at *10. This Court reversed dismissal because the public disclosures did not "present the full picture of fraud"—*i.e.*, the disclosures did not clearly assert X (that the defendant claimed the use of its patent "was not obvious" and the patents "were original discoveries") and Y ("the alleged truth" that the use was obvious and so the "patents were invalidly obtained"). *Id.* at *10-11. The Court held that the "scattered qualifying public disclosures" there each contained "a piece of the puzzle," but did not "stitch[] together" both X and Y. *Id.* at *11. Here, by contrast, the *Army Times* article and Federal Register independently and in tandem neatly stitch together both X and Y—*i.e.*, that ESI allegedly was over-dispensing medication by automatically shipping beneficiaries 90 pills every 60 days while DoD was paying for this excessive medication pursuant to the TMOP program—such that Z, the fraud Relators allege here, is easily inferred. Thus, the disclosures revealed the necessary "pieces of the puzzle" to reasonably—and in this case easily—infer the alleged fraud under the standards enunciated in *Mateski* and *Silbersher*.[12]

[12] It is simply not true, as Relator assumes without citation, that the public disclosures need to include details about how ESI's practices deviated from its prior practice, violated prescribing orders, or broke industry standards in doing what the

The public disclosures contain more than the information needed to alert the government to potential fraud and prompt investigation, which is all that is required to trigger the bar. *See United States ex rel. Hastings v. Wells Fargo Bank, N.A.*, 2014 WL 3519129, at *9 (C.D. Cal. 2014) (bar applies "so long as the disclosure contains sufficient information to enable the government to investigate the alleged fraud"), *aff'd*, 656 F. App'x 328 (9th Cir. 2016); *United States ex rel. Sanches v. City of Crescent City*, 2010 WL 4696835, at *5 (N.D. Cal. 2010) (report indicating defendant housing authority's "administrative fees reserve … accumulated funds exceeding the required 105% cap" contained the material elements of fraud). Here, the government has even more information than typical, since it is the party contracting with ESI and would have direct knowledge of any contract violation.

Further, this case, unlike *Mateski*, does not involve a public disclosure revealing only "problems" in contract performance or "generalized fraud." Relator Br. 33 (quoting *Mateski*, 816 F.3d at 577); *see also Mark ex rel. United States v. Shamir USA, Inc.*, 2022 WL 327475, at *2 (9th Cir. 2022) (memorandum decision cited by Relator holding that a defendant's own promotion materials including "a generalized description of a program" as offering patients "automatic[] rewards back" (obviously) did not disclose a transaction or allegation of fraud). Rather, the

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Army Times article said it was doing. *See* Relator Br. 39. Tellingly, Relator describes these allegations as providing more "details," *id.*, which Ninth Circuit law says cannot defeat substantial similarity. *E.g.*, *Solis*, 885 F.3d at 627.

public disclosures here identified "the same actor[]" and "the same conduct" as the Complaint, and provided specific examples underlying the core fraudulent transaction—putting the government on notice to investigate. *Solis*, 885 F.3d at 626.

B. Relator Is Not an Original Source.

The district court was also correct to hold that Relator is not an "original source" and, thus, the public-disclosure bar applies. 1-ER-026-32.

Under the current version of the FCA, an original source is (as relevant here) "an individual who … has ***knowledge that is independent of*** and ***materially adds to the publicly disclosed allegations or transactions***." 31 U.S.C. § 3730(e)(4)(B) (2010) (emphases added). Under the 1986 version of the statute, there was no "materially adds" requirement, but a relator's knowledge had to be both independent and "direct." Relator fails all these requirements.

1. Relator—an LLC Created for the Purpose of this Litigation and Without Any Direct or Independent Knowledge—Cannot Be an Original Source.

Relator has neither direct nor independent knowledge of the alleged fraud. To show "direct" knowledge, a relator "must show that he had firsthand knowledge of the alleged fraud, and that he obtained this knowledge through his 'own labor unmediated by anything else.'" *United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1020 (9th Cir. 1999) (citation omitted). "To prove 'independent' knowledge, relators have to show they had relevant 'evidence of fraud prior to the public

disclosure of the allegations.'" *Amphastar*, 856 F.3d at 705 (quoting *United States ex rel. Devlin v. California*, 84 F.3d 358, 361 n.5 (9th Cir. 1996)).

a. *Relator Lacks "Direct" Knowledge Under the 1986 Bar.*

As relevant to the 1986 bar, the district court correctly held that Relator did not have direct knowledge—knowledge obtained unmediated and firsthand from ***Relator's*** own labor. 1-ER-026-28. Indisputably, Relator (3729, LLC) "did not discover firsthand the information underlying [its] allegations of fraud." *Devlin*, 84 F.3d at 361. At best, 3729, LLC derived this information secondhand. 3729, LLC did not come into existence until May 29, 2019—three years after the most recent conduct alleged in the Complaint, and less than a month before the lawsuit was filed. *See* 3-ER-284.

To the extent the LLC received any information at all, Relator concedes it received it from the PIC—one of the LLC's principals. Relator Br. 54. The PIC was not working with Relator at the time he learned the information (because 3729, LLC did not exist yet). Instead, Relator received any information from the PIC years later—and well after the public disclosures at issue.

Indeed, Relator tacitly recognizes that ***it***—3729, LLC, the only Relator and Appellant in this case—does not have direct knowledge by arguing that "Relator acquired its knowledge directly from its own members, including the PIC Relator, who indisputably had 'firsthand knowledge' of ESI's fraud." *Id.* In other words,

Relator acquired its knowledge of ESI's alleged fraud secondhand from "the PIC." *Id.* And calling the pharmacist-in-charge "the PIC Relator" is pure fiction. *Id.*; *see also id.* at 53 n.5, 58. The PIC is ***not*** the Relator in this case, and the firsthand knowledge of a non-relator is irrelevant.

Relator hopes its members' knowledge may be imputed to it such that it may also be said to have "direct" knowledge (*id.* at 55-58), but the district court properly held that case law forecloses that argument. Focusing on whether 3729, LLC itself meets the statutory definition is a natural result of a bedrock principle that "LLCs are distinct legal entities, separate from their stockholders or members." *Abrahim & Sons Enters. v. Equilon Enters., LLC*, 292 F.3d 958, 962 (9th Cir. 2002); *see also United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 554 (10th Cir. 1992) (assessing whether corporate relator qualified as original source rather than its shareholders and affirming dismissal because corporate relator did not have requisite direct or independent knowledge).

3729, LLC therefore cannot stand in the shoes of its members. *See United States ex rel. Alexander Volkhoff, LLC v. Janssen Pharm. N.V.*, 945 F.3d 1237, 1244-45 (9th Cir. 2020) (refusing to treat "LLC [a]s interchangeable with a natural person" in FCA's first-to-file context). A similar situation arose in *CKD Project*, where an LLC relator was formed for the purpose of bringing a *qui tam* action, arguing its knowledge of the fraud came from an "inside participant in one of the fraudulent

joint venture transactions." *United States ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, 551 F. Supp. 3d 27, 33 (E.D.N.Y. 2021), *aff'd*, 2022 WL 17818587 (2d Cir. 2022); *see id.* at 34 n.2 (analyzing meaning of original source under both pre- and post-2010 amendment versions of the statute). The court rejected this argument, holding that the relator was "not a whistleblower, but an entity formed solely for this litigation" that "acquired its information from a third party." *Id.* at 33. Other courts have similarly ruled that corporate relators created for litigation lack the requisite knowledge of an original source. *See Precision*, 971 F.2d at 554 (finding corporate relator was not an original source of information its shareholder and president obtained "prior to its formation").

This rule is not only supported by the case law, but it makes eminent sense. The FCA limits original sources to "individual[s]" with direct and/or independent knowledge. 31 U.S.C. § 3730. That limitation aims to reward and incentivize whistleblowers, not entities "formed solely for [purposes of] litigation" that acquire knowledge secondhand. *CKD Project*, 551 F. Supp. 3d at 33. The alternative rule "would allow persons other than the original source to benefit merely by showing that they were somehow deputized by the original source to file the suit." *United States ex rel. Fed. Recovery Servs., Inc. v. Crescent City E.M.S., Inc.*, 1993 WL 345655, at *4 n.12 (E.D. La. 1993) (rejecting argument that corporate relator created

for purpose of litigation was "agent" of, and had a right to information collected by, shareholder), *aff'd*, 72 F.3d 447, 451-53 (5th Cir. 1995).

3729, LLC cannot know any of the information or facts its members purport to know unless those members gained that knowledge while acting within the scope of their authority on behalf of the LLC. *See Am. Gen. Life Ins. Co. v. Darbinyan*, 2022 WL 1134722, at *8 (C.D. Cal. 2022) ("If [an agent] does not acquire [knowledge] while acting within the scope of his authority, the knowledge is no more to be imputed to the principal than to an utter stranger."). Relator's own authority confirms this. Relator cites (at 55) *Minnesota Association of Nurse Anesthetists v. Allina Health System Corp.*, but that case held corporations would not have knowledge if they were "formed after the information had been discovered and disclosed by people who became shareholders of the corporations," explaining that, in those cases, "the corporations were not original sources of the information." 276 F.3d 1032, 1049 (8th Cir. 2002). The court further explained that a "corporation has no standing to assert rights belonging to its shareholders," which is exactly what 3729, LLC is attempting to do here. *Id.* at 1050.[13]

[13] Relator also cites *United States ex rel. Springfield Terminal Ry. Co. v. Quinn* (at 57), but in that case, the corporate relator was not formed to bring the FCA action, instead discovering the alleged fraud in the course of its separately existing affairs (during a separate litigation). 14 F.3d 645, 656-57 (D.C. Cir. 1994).

Here, no member was acting on behalf of the LLC when he/she gained any relevant knowledge because 3729, LLC was formed after its eventual members obtained the knowledge. *See Precision*, 971 F.2d at 554. There could be no principal-agent relationship before the LLC existed. *Am. Gen. Life Ins.*, 2022 WL 1134722, at *8. The mere fact that a corporation may acquire direct or independent knowledge through its members regarding actions taken on its behalf, *see* Relator Br. 55-56 (citing cases, including *United States ex rel. STF, LLC v. Vibrant Am., LLC*, 2020 WL 4818706, at *19 (N.D. Cal. 2020)), does not mean that it acquires such knowledge when formed well after individuals obtained the knowledge at a time when they had no connection to the corporation.[14]

As the district court held, "Relator does not have direct knowledge of the information collected by its principals from before its formation … less than a month

[14] Relator puzzlingly quotes the Restatement of Agency's "Imputation of Notice of Fact to Principal" section, which notes that notice of a fact "is imputed to the principal" only "[w]hen an agent is aware of a fact at the time of taking authorized action on behalf of a principal and the fact is material to the agent's duties to the principal." Restatement (Third) of Agency § 5.03(e) (2006). But, of course, Relator identifies no action the PIC took on Relator's behalf or how this knowledge is material to the PIC's duties to Relator. The same Restatement comment also says: "Information that an agent learns in confidence from one principal is not imputed to another principal." *Id.*

Moreover, at most, even under Relator's argument, the knowledge would be imputed to Relator ***then***—"at the time [the agent took] authorized action on behalf of a principal"—not six years earlier, before the Relator even existed, so it would not be "independent" knowledge. *See infra* Section I.B.1.b.

before it filed this action." 1-ER-028. Filing this action on behalf of 3729, LLC rather than any individual was a "tactical choice," which has consequences. *Alexander Volkhoff*, 945 F.3d at 1245. 3729, LLC has no direct knowledge and thus is not an original source under the 1986 statute.

b. *Relator Lacks "Independent" Knowledge Under the 1986 and 2010 Bars.*

The Relator entity being formed just weeks before the Complaint was filed for the sole purpose of bringing this lawsuit also confirms Relator cannot have ***independent*** knowledge—a requirement under both the 1986 and 2010 statutes (though largely ignored in Relator's brief). Simply put, Relator did not exist before the public disclosure. Its knowledge therefore cannot have been acquired "prior to the public disclosure of the allegations" as required under both versions of the statute. *Amphastar*, 856 F.3d at 705; *see id.* at 702 n.8, *Devlin*, 84 F.3d at 361 n.5.

The pre-2010 requirement that "independent knowledge" must be acquired "prior to the public disclosure" remains the same after the 2010 amendment. *Sam Jones*, 2023 WL 2993409, at *5; *Silbersher v. Allergan Inc.*, 2023 WL 2593777, at *10 (N.D. Cal. 2023) ("While *Amphastar* interpreted the pre-2010 version of 'original source,' the Court finds nothing in the amended definition to suggest that the meaning of 'independent' has changed."), *appeal pending*. So, under both versions of the statute, Relator's lack of any knowledge prior to the public disclosures means it cannot be an original source. *See Amphastar*, 856 F.3d at 705.

And, as discussed above, *supra* pp. 32-35, even assuming that the knowledge of the former PIC is "independent," that knowledge (acquired before 3729, LLC existed and outside the scope of the PIC's relationship to 3729, LLC) cannot be imputed to Relator. *See, e.g.*, *Abrahim & Sons*, 292 F.3d at 962; *Am. Gen. Life Ins.*, 2022 WL 1134722, at *8 (knowledge of agent imputed to principal "only when" agent acquires knowledge "in the course of his agency").

3729, LLC cannot claim it knew of events occurring years before its incorporation based on one of its members' purported knowledge. Relator is therefore not an original source under either version of the statute.

2. Relator's Allegations Do Not Materially Add to the Public Disclosure.

The district court was also correct to hold that Relator is not an original source under the 2010 statute for the additional reason that the Complaint does not "materially add" to the public disclosure. *See* 1-ER-029-32; *Sanches*, 2010 WL 4696835, at *7 ("If … someone republishes an allegation that already has been publicly disclosed, he cannot bring a *qui tam* suit, even if he had 'direct and independent knowledge' of the fraud." (citation omitted)).

Where allegations "provide only background information and details relating to the alleged fraud," they "do not materially add to public disclosures." *Hastings*, 656 F. App'x at 331-32; *see also United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 213 (1st Cir. 2016) (information that "merely adds detail or

color to previously disclosed elements of an alleged scheme" does not materially add). Allegations must materially "add value to what the government already knew," or change the government's investigation in a material way. *Hastings*, 656 F. App'x at 331-32.

The Complaint does not materially add to the alleged fraudulent transaction about which the government was already on notice; at most, it adds background information, detail, or color. The *Army Times* article and the Federal Register already alleged that ESI was causing significant waste through its auto-refill program, including by shipping 90 days' worth of medication every 60 days, resulting in stockpiles of scripts in beneficiaries' medicine cabinets and excessive dispensing fees charged to the government. *See supra* Section I.A. This is precisely the conduct that Relator alleges is fraud and upon which its claims are centered—ESI dispensing 90-day prescriptions every 60 days and thereby dispensing in a manner that is excessive. *See* 3-ER-339 (Compl. ¶2); 3-ER-349 (Compl. ¶34); 3-ER-352 (Compl. ¶44); 3-ER-367-68 (Compl. ¶¶110-12). Nothing 3729, LLC (or its principals) brought to the table is different from what was already publicly disclosed.[15]

[15] Moreover, the disclosures were not just public, but the government actually read and reviewed them. ESI sent the *Army Times* article to DHA at the agency's request and the Federal Register states that the DoD received, read, and considered the relevant comments. *See* 3-ER-398 (Dist. Ct. Dkt. 59 (filed under seal separate from ER)); 81 Fed. Reg. at 76,309.

The district court was right (at 1-ER-031) to analogize this case to *Sanches*, where additional information and details about false certifications (which were not included in the public disclosures) were "not necessary" and did not add to what had been disclosed about funds exceeding the 105% cap. 2010 WL 4696835, at *7-8 (not original source where complaint and disclosures both contain "the material elements that depict fraud"). "Here, as in *Sanches*, the additional allegations in Relator's Complaint do not add materially to what already had been disclosed by the *Army Times* article and DoD final rule." 1-ER-031.

The additional color that Relator adds is just that—color. Its Complaint merely adds detail to what was previously disclosed, which is insufficient to meet the "materially adds" standard. *See Winkelman*, 827 F.3d at 213 (allegations regarding "the precise manner in which" a defendant "operated [its] program" only add color and do not "materially add[] to the public disclosures"); *CKD Project*, 2022 WL 17818587, at *4 (including more specific details of publicly disclosed information did not materially add to disclosures). Relator alleges a broad date range for the fraud (3-ER-339-40 (Compl. ¶3)); it provides the names of certain individuals who oversaw the automatic refill program and were allegedly involved in implementing and modifying the software ESI used (3-ER-354-55 (Compl. ¶55); 3-ER-360-61 (Compl. ¶¶79-80); 3-ER-365 (Compl. ¶113)); and it claims the former PIC discussed his concerns regarding over-refilling prescriptions with certain ESI

employees (3-ER-362 (Compl. ¶¶88-89)). These allegations, however, are "background information" and do not inform the government in any material way. *See Winkelman*, 827 F.3d at 212 ("Offering specific examples of that conduct does not provide any significant new information where the underlying conduct already has been publicly disclosed.").[16]

Other cases from this Circuit readily hold that such information does not materially add to the prior public disclosures. In *Hastings*, the Ninth Circuit found that a relator was not an original source where it provided "background information and examples of loans that had been made using seller-funded down payment assistance programs" because the government was already aware of these programs,

[16] It is also notable that much of the Complaint provides background or context ***from public sources***, not Relator's or its principals' knowledge. Among the public sources relied on in the Complaint are reports from the U.S. Department of Health and Human Services (3-ER-344 (Compl. ¶15)) and the DoD IG (3-ER-363 (Compl. ¶94)); congressional hearings (3-ER-345 (Compl. ¶18)); published letters from the Centers for Medicare and Medicaid (3-ER-345 (Compl. ¶19)); and published online complaints (3-ER-353-54 (Compl. ¶¶50-52)). Relator expressly acknowledges it relied "on public filings" to reach the conclusion that ESI "was able to book revenue" and therefore increase "its profit margins" for "each dispensing event." 3-ER-360 (Compl. ¶78). And in discussing ESI's supposed cover-up, Relator's chief example is a 2013/2014 DoD IG audit report, a public report which also says nothing of a supposed cover-up. That report publicly stated that while the auditors had "'attempted to obtain information' on waste resulting from 'delivered, unneeded prescription medications,' ESI had claimed that it 'could not provide [such] data,' and thus the auditors were not able to review 'patient utilization of their medications.'" Relator Br. 13 (citing the Complaint and the audit report itself). Even if this background came from Relator (it did not), it would not suffice to materially add. *See Solis*, 885 F.3d at 627 (noting "the few unique details about the studies" in the relator's complaint would not be "material to a government investigation").

as they were the subject of proposed rules, audits, a GAO report, and congressional hearings. 656 F. App'x at 332. Similarly, in *North American Health Care*, the relator alleged that defendants engaged in fraudulent billing practices by "upcoding" for services not rendered and by providing unnecessary therapies. 173 F. Supp. 3d at 947-48. There, a news article already alleged that defendant was engaged in these practices. *Id.* at 948. Courts in other circuits have reached the same conclusion. For instance, in *CKD Project*, the relator was not an original source even though the complaint "paint[ed] a clearer picture of the alleged fraud," including "more specific facts" "about how the joint ventures" were arranged and "when and how" they were executed, but it did "not considerably add to the [material] information already available to the public." 551 F. Supp. 3d at 46-47.

As in *Hastings*, *North American Health Care*, and *CKD Project*, Relator's Complaint falls well short of materially adding to the public disclosures. The core aspects of the Complaint were disclosed through the *Army Times* article and the Federal Register. The Complaint's background information regarding the individuals involved in the auto-refill program, its mechanics, and the financial incentives underlying it does not materially add to the alleged scheme.

Relator makes several arguments for how it supposedly materially added to the public disclosures. Each fails.

First, Relator argues that its allegation regarding how ESI coded its software materially adds to the disclosures. *E.g.*, Relator Br. 49. It does not. When a relator provides more detail about how the defendant "operated [its] program," it "merely adds detail or color to previously disclosed elements of an alleged scheme," which falls short of materially adding. *Winkelman*, 827 F.3d at 213; *see also CKD Project*, 2022 WL 17818587, at *4 (relator was not original source where allegations included specific details regarding disclosed information); *Calva*, 2018 WL 6016152, at *8 ("allegations add[ing] detail about the precise methodology Impac Defendants used to measure delinquency rates that made the disclosures … false and misleading" did not materially add). In *Winkelman*, one of the relators argued that she materially added to disclosures by alleging, among other things, "that [defendant's] ***computer programming was tailored to facilitate the scheme***." 827 F.3d at 213 (emphasis added). The court rightly rejected that argument, finding those allegations "add detail about the precise manner in which CVS operated the HSP program" (or the "how" of the fraudulent scheme), which does not materially add to fraud allegations. *Id.*

Likewise, in *Rahimi*, the relator argued he "materially added" in part because he included allegations that "Rite Aid's billing systems took [usual and customary] prices into account when computing charges to government payers." 3 F.4th at 831. Those allegations did not "materially add to the public disclosures because the

government was already on notice that Rite Aid had not been applying" discounted prices to its pricing calculations. *Id.*

Here, Relator's allegations that ESI "calibrated its dispensing software so that" refill requests resulted in "a full 90-day supply" of medication every 60 days do not "materially add" because the government was similarly already on notice that ESI allegedly was over-dispensing. 3-ER-350 (Compl. ¶¶36-39). The idea that ESI implemented its auto-refill practice through a "pharmacy dispensing software" (3-ER-350 (Compl. ¶36)) is both obvious and adds nothing material to the government's ability to investigate the public allegation. The district court was right to hold that providing additional "detail about the precise methodology" ESI used to "perpetuate the alleged auto-refilling fraud" does not materially add. 1-ER-031 (quoting *Calva*, 2018 WL 6016152, at *8).

Second, Relator says it materially added by naming the "ESI executives and employees who oversaw the scheme." Relator Br. 48. But its own cases, including *United States ex rel. Reed v. KeyPoint Government Solutions*, make clear that "identifying individual [persons] as wrongdoers" does not "materially add" because it "merely adds detail or color to previously disclosed elements of an alleged scheme." 923 F.3d 729, 759 (10th Cir. 2019) (quoting *Winkelman*, 827 F.3d at 213); *id.* at 760 ("if identifying new employees engaged in fraud were enough, the original-source exception would burst from overbreadth").

Third, Relator argues that it revealed a purported "cover-up" which somehow materially adds to the public disclosures. Relator Br. 33. Not so. As a matter of logic, alleging that a defendant concealed or covered up the alleged fraud, which itself had been publicly disclosed, does not add ***any*** information about the underlying fraudulent scheme. Unsurprisingly, the limited case law on this point agrees with this logical proposition, holding that allegations regarding "efforts to cover up the alleged fraud scheme … do not materially add to the core fraud allegations themselves, which already were publicly disclosed." *United States ex rel. Jacobs v. JP Morgan Chase Bank, N.A.*, 2022 WL 573663, at *7 (S.D. Fla. 2022), *appeal pending*. Moreover, cases have held that a relator alleging that previously disclosed fraud continued after the public disclosure does not materially add to the disclosures because the core alleged fraud were already disclosed. *See N. Am. Health Care*, 173 F. Supp. 3d at 951 ("Where the allegations are simply that the same fraud previously disclosed is ongoing, those allegations will be barred."). If that is so, then alleging simply that a defendant attempted to cover up previously disclosed fraud adds even less to the fraudulent scheme.

Moreover, the Complaint's allegations that Relator refers to as a "cover-up" involve no such thing. *See* Relator Br. 33 (citing 3-ER-363-66 (Compl. ¶¶94-105)). Rather, this portion of the Complaint refers exclusively to the DoD's public IG audit and mostly complains about the ***government's*** choice to conduct a supposedly "very

narrow" audit and failure to "evaluate[] the logic of Express Scripts' dispensing software or review[] a statistical sample of auto-refill prescriptions." 3-ER-365 (Compl. ¶¶102, 104). And in asserting that ESI "withheld information from the auditors," Relator does nothing but quote the IG's public report itself, which stated that IG auditors "attempted to obtain information" regarding "delivered, unneeded prescription medications" but ESI "could not provide" certain data. 3-ER-365 (Compl. ¶103 (quoting report)). Of course, quoting the government's own reports does not materially add to the government's information—and the Complaint does not allege that ESI in fact could provide this information, which would depend on ESI knowing whether a beneficiary used certain medication (information it does not have, as the IG report noted).

Fourth, and tellingly, Relator relies almost exclusively on out-of-circuit case law to describe what it means to materially add under the 2010 statute—despite itself admitting that "different circuits have interpreted" that requirement differently. Relator Br. 44; *see id.* at 44-47. What matters here is how the Ninth Circuit describes the applicable standard—and the chief case (*Hastings*) makes clear that additional "background information and details relating to the alleged fraud … do not materially add to public disclosures," 656 F. App'x at 331-32, despite Relator's reliance on out-of-circuit cases saying that additional "factual background" does materially add. Relator Br. 45 (citing cases); *see, e.g.*, *United States ex rel. Fadlalla*

v. DynCorp Int'l LLC, 402 F. Supp. 3d 162, 185-86 (D. Md. 2019) (holding without much discussion and clearly contrary to Ninth Circuit law that "firsthand experiences" and details necessarily materially add).[17]

Relatedly, Relator resorts to hyperbole, claiming the district court's reasoning means "virtually no relator … can qualify as an original source if the 'core fraud allegations' were previously disclosed, an interpretation that reads the 'original source' exception out of the FCA." Relator Br. 21; *see id.* at 50-53. That is not so. Rather, Relator's allegations do not materially add ***in this case*** because the public disclosures already put the government on the trail of the exact same fraudulent

[17] Relator also misapplies those cases. For example, Relator implies (at 50) that *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 306 (3d Cir. 2016), held the original source exception "comes into play" when the "core fraud allegations" are publicly disclosed and the relator adds more detail, but the quote from *Moore* is that the exception may apply "only when some facts regarding the allegation or transaction" are disclosed, *id.*, not when—as here—the "core fraud allegations" are already disclosed. Relator also relies on *Reed* from the Tenth Circuit, but that case held the relator materially added because she revealed an entirely "new scheme[] to defraud the government"—alleging fraud in a "distinct context" from the public disclosures, which simply related to "problems in the industry" and shoddy investigations. 923 F.3d at 760-62. Unlike the *Reed* allegations "blaz[ing] a new trail" of a "new fraudulent scheme," the allegations here simply "add a few more breadcrumbs on an existing trail." *Id.* at 762-63. *Reed* also explicitly rejected *Moore*'s framework for materially adds because it would "allow the original-source exception to swallow the public disclosure bar" by permitting mere "detail or color" to materially add. *Id.* at 758.

Relator also cites (at 44, 49) cases analyzing the pre-2010 statute, which are irrelevant to the "materially adds" question. *See Baltazar*, 635 F.3d 866; *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009).

scheme in the Complaint. Further, this case involves the performance of a detailed contract directly between ESI and the government, and thus the government already had direct knowledge of the requirements of the contract.

Even assuming *arguendo* that Relator's allegations would materially add to prior disclosures that simply alleged waste or excessive prescription refills, the *Army Times* article specifically identified sending 90 pills every 60 days as a means by which ESI engaged in excessive refills. The government had everything it needed to investigate that potential fraud, and Relator simply alleging that ESI in fact intentionally sent 90 pills every 60 days to its beneficiaries, or did so through computer software, does not materially add to that investigation. This case is different from one like *Reed*, where the relator alleged a "new scheme[] to defraud the government" in a different context. 923 F.3d at 760. Here, just like in *Calva*, Relator's allegations at most "add detail about the precise methodology" used to effectuate the same scheme—and those details do not change that "the false and misleading disclosures were already publicly disclosed." 2018 WL 6016152, at *8.[18]

Finally, the district court was also right to reject Relator's insistence that one of its members (the PIC of one of ESI's locations) being an insider during the years of the alleged fraud is sufficient to make it (or even the PIC) an original source of

[18] Relator's *amicus* makes similar arguments also divorced from the facts in this case. *See* ECF No. 21-1 at 13-16; *see id.* at 7-13 (discussing policy behind FCA generally and ignoring the disclosures and allegations here).

the allegations. *See* 1-ER-032 n.9. "*Qui tam* suits are meant to encourage insiders privy to a fraud on the government to blow the whistle on the crime." *United States ex rel. Fine v. Chevron, U.S.A., Inc.*, 72 F.3d 740, 742 (9th Cir. 1995) (en banc). The FCA does so by rewarding "those brave enough to speak in the face of a 'conspiracy of silence,' and not their mimics." *Wang v. FMC Corp.*, 975 F.2d 1412, 1419 (9th Cir. 1992). If, by contrast, an insider sits on her hands, not blowing the whistle, and later forms a shell entity to anonymously file a meritless and parasitic *qui tam* suit based on publicly disclosed information, she cannot later be deemed an "original source" even if she had independent knowledge unless the information ***materially adds*** to the fraudulent scheme already disclosed, an appropriately high bar. If not, she did not come forward promptly enough (*i.e.*, before the public disclosures) and is not an original source. *See* 1-ER-032 n.9.

II. Dismissal Should Be Affirmed for the Alternative Reason that the Complaint Failed to State a Claim.

Defendants also moved to dismiss the Complaint for failure to state a claim. *See* 3-ER-237-45. The district court did not "reach the sufficiency of Relator's allegations" because it held "dismissal is warranted under the public-disclosure bar." 1-ER-012. That said, this Court can affirm "on any ground raised below and fairly supported by the record," *Ranza v. Nike, Inc.*, 793 F.3d 1059, 1076 (9th Cir. 2015) (citation omitted), and the deficiencies in Relator's FCA claim are clear from the face of the Complaint—providing alternative grounds to dismiss.

To state a claim under the FCA, a relator must allege: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Adomitis ex rel. United States v. San Bernardino Mountains Cmty. Hosp. Dist.*, 816 F. App'x 64, 66 (9th Cir. 2020) (citation omitted). In considering whether a relator has met that burden, courts accept as true all "well-pleaded factual allegations" in the Complaint but are not "bound to accept as true a legal conclusion couched as a factual allegation." *Ashcroft*, 556 U.S. at 678-79. And Rule 9(b)'s heightened pleading standard applies. *United States v. Safran Grp.*, 2017 WL 235197, at *6 (N.D. Cal. 2017).

A. Relator Has Not Alleged Falsity.

The Complaint proceeds under a theory of legal falsity by alleging that ESI's dispensing practices resulted in "excessive" or "flagrant and persistent overutilization" in violation of federal regulations and contractual requirements. 3-ER-349 (Compl. ¶35); 3-ER-352-53 (Compl. ¶¶46-47). But the regulations that Relator cites and the government's pre-2021 contracts with ESI are silent as to how frequently and in what quantities medication should be dispensed and refilled. Neither they, nor the Complaint, provide any objective benchmark that governed ESI's obligations at the time. Accordingly, the Complaint does not plead legal falsity under the FCA.

To adequately plead a legally false claim, a relator must identify a specific contract provision or regulation with a clear benchmark or objective threshold that a defendant violated. *See United States ex rel. DeFatta v. United Parcel Serv., Inc.*, 771 F. App'x 735, 738 (9th Cir. 2019) (affirming dismissal where relator could not show defendant violated contractual provisions regarding proper shipping methods); *United States ex rel. O'Neill v. Somnia, Inc.*, 339 F. Supp. 3d 947, 955-57 (E.D. Cal. 2018) (granting motion to dismiss because relator failed to show that regulation prohibited defendant's conduct). Yet the regulations and contracts are silent as to how frequently medication (that was clearly prescribed in the quantity dispensed) should be dispensed and refilled. Relator therefore has provided no clear benchmark or objective threshold that ESI's dispensing practice allegedly violated.

The Complaint makes generalized allegations that ESI failed to prevent fraud, waste, and abuse in the Tricare program, and engaged in "flagrant and persistent overutilization of services" through its "excessive dispensing practices" in violation of 32 C.F.R. § 199.21 and 32 C.F.R. § 199.9(c), respectively. *See* 3-ER-347 (Compl. ¶25); 3-ER-349 (Compl. ¶35); 3-ER-352-53 (Compl. ¶¶46-47). It also alleges ESI failed to give "proper regard" for patients' needs and physicians' orders, 32 C.F.R. § 199.9(c)(5), and violated various state pharmacy regulations, with which ESI was required to comply while providing TMOP. *See* 3-ER-348-49 (Compl. ¶¶31-33); 3-

ER-355-56 (Compl. ¶¶58, 61-62); 3-ER-358 (Compl. ¶¶69-70); 3-ER-359 (Compl. ¶¶74-75).

The regulations and provisions that the Relator cites, however, do not provide objective standards defining what constitutes "overutilization" or "proper regard" in this context and thus no guideposts to establish that ESI's well-publicized filling practices were otherwise. Absent such objective standards or guideposts, Relator cannot allege falsity under the FCA. *See United States ex rel. Whatley v. Eastwick Coll.*, 657 F. App'x 89, 94 (3d Cir. 2016) (affirming dismissal of *qui tam* complaint based on allegations schools used federal financial aid for exorbitantly priced books and fees because relator failed to specify a statute, regulation, or contractual provision establishing permissible price range); *cf. Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 195-96 (2016) (an allegation that the defendant certified compliance with all laws would be insufficient to state FCA claim). Instead, it alleges that ESI violated some generalized standard of conduct, which is insufficient to allege falsity in FCA cases. *See United States v. McKesson Corp.*, 2020 WL 4805034, at *4-5 (N.D. Cal. 2020) (granting motion to dismiss where relator alleged violations of regulations that did "not require any specific security measures and instead" allowed for discretion).

Moreover, Relator has not pointed to any contractual provision that ESI allegedly violated through its dispensing practices. Nor can it. The relevant TMOP

contracts did not impose specific dispensing guidelines. Rather than impose specific dispensing limits and requirements, ESI's contracts with DHA authorized ESI to administer the TMOP based on "best commercial practice." 3-ER-258 § C.2.3; *see* 3-ER-266 § C.7.1.10 ("Contractor may offer automatic refills").

When the government included a contractual provision defining the appropriate amount of prescription on hand for the first time in ESI's 2021 contract, it adopted medication dispensing practices like those ESI already had in place by explicitly authorizing it to dispense "450 days' supply" of medication (five 90-day refills) "over the course of [] 365 day[s]." 3-ER-278 § C.6.1.23.4. Far from proscribing ESI's conduct, this provision expressly permits dispensing practices resulting in the delivery of medication in quantities well in excess of what was prescribed. Relator cannot make out an FCA violation based on allegations of dispensing excessive quantities of mediation but lacking any objective benchmarks, especially where the delivery of medication substantially in excess of quantities never prescribed was not prohibited by ESI's contracts with the government and is now expressly permitted. *See Parker v. Sea-Mar Cmty. Health Ctr.*, 853 F. App'x 197, 198 (9th Cir. 2021) (affirming dismissal of *qui tam* complaint because

defendant's statements could not be false if not prohibited by statute, regulations, or guidance); *McKesson*, 2020 WL 4805034, at *4.[19]

Below, Relator relied on *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr.*, 953 F.3d 1108 (9th Cir. 2020), but that case supports ESI. In *Winter*, the relator alleged a hospital admitted patients in violation of a statute requiring medical services to be "medically necessary." However, medical necessity is a well-recognized and oft-used term of art that easily provides the requisite objective standards. *See id.* at 1113. This Court held that a physician's assessment that "hospitalization was 'medically necessary' can be false" because it could be proven that it was not "in accordance with accepted standards of medical practice." *Id.* at 1119. Accepted standards of medical practice are the very type of defined objective standards missing here. In contrast, here, Relator offers nothing other than its own subjective opinion as to what is "excessive."

[19] Furthermore, insofar as 3729, LLC claims that ESI acted improperly by automatically enrolling beneficiaries in the automatic refill program, thereby causing the submission of a false or fraudulent claim (3-ER-351 (Compl. ¶ 42); 3-ER-357-58 (Compl. ¶¶ 63-69)), its allegations likewise fail. The Complaint and the 2013 DoD IG Report cited therein (3-ER-363 (Compl. ¶ 94 & n.10)) describe the auto enrollment program in the same way, yet the Report commends the program. *See* 3-ER-327. The government both knew of and approved of the conduct underlying Relator's allegations regarding automatic enrollment. ESI therefore cannot have submitted a false claim. *See United States v. Shasta Servs., Inc.*, 440 F. Supp. 2d 1108, 1113-14 (E.D. Cal. 2006) (finding defendant did not submit false claim and granting motion to dismiss because government had knowledge of circumstances surrounding conduct).

B. Relator Has Not Alleged Materiality.

Dismissal should likewise be affirmed for the independent reason that the Complaint fails adequately to allege materiality. The standard for materiality is rigorous and "False Claims Act plaintiffs must … plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Escobar*, 579 U.S. at 195 n.6; *see also United States v. San Bernardino Mountains Cmty. Hosp. Dist.*, 2018 WL 5266867, at *9 (C.D. Cal. 2018) (granting motion to dismiss with prejudice where relator failed to plead materiality), *aff'd*, 816 F. App'x 64.

Liability under the FCA arises only for misrepresentations that are material to the government's decision to pay a claim. *Escobar*, 579 U.S. at 181. "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* at 194. If the government continues to pay certain claims "despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id.* at 195; *United States v. TruConnect*, 2020 WL 13534177, at

*8 (C.D. Cal. 2020) (granting motion to dismiss for lack of materiality where government continued making payments despite knowledge of alleged fraud).

The Complaint makes conclusory claims that the government would not have paid ESI had it known of the alleged fraud, but it alleges no facts to support that claim. Moreover, the Complaint and documents referenced therein make plain that the government continued to pay the claims even though it had actual knowledge of ESI's dispensing practices via the public disclosures. DHA began paying ESI's automatic refill claims in 2008 and continues to do so today, despite having been made aware of allegations in the *Army Times* article in 2013. In 2013, the DoD acknowledged that ESI's practices could lead to "increased waste [of] 57 percent" and yet concluded they were no more wasteful than other 90-day supply refill programs. 3-ER-326. DHA then investigated the alleged over-refilling in 2015 and the DoD's rulemaking publicly disclosed these allegations in 2016. Further, in the 2017 DoD IG Report cited in the Complaint, the DoD publicly stated that it considered "beneficiaries who exceeded quantity limits solely due to the refill date to be compliant with quantity limit controls." 3-ER-308 n.12. Knowing all this, the government has renewed its contract with ESI twice, in 2014 and 2021. That latter renewal was after the Complaint was filed and expressly permitted ESI to dispense far more than 365 days of medication in a single year. 3-ER-278 § C.6.1.23.4.

Moreover, ESI has submitted monthly reports to the government regarding prescriptions filled by beneficiaries, including date filled, quantity, and days' supply dispensed for individual claims. 2-ER-160 § C.11.5.1.2; 2-ER-163. ESI also transmitted all claim information to a government database and provided the government with access to ESI's own database that included "all claim information." 2-ER-157-58 § C.1.5; 2-ER-160-62 §§ C.12.2, C.12.4.1. As a result, the government had all the data it needed to determine whether and to what degree it was billed for extra medication.

Thus, the government's behavior—based on the Complaint and documents referred to or incorporated in the Complaint—shows that Relator's allegations are immaterial. *See United States ex rel. Zissa v. Santa Barbara Cnty. Alcohol, Drug & Mental Health Servs.*, 2019 WL 3291579, at *6 (C.D. Cal. 2019) (granting motion to dismiss because government knew of alleged violations and continued making payments, which was "strong evidence against materiality") (citing *Escobar*, 579 U.S. at 195); *see also United States ex rel. Petratos v. Genentech*, 855 F.3d 481, 490 (3d Cir. 2017) (finding lack of materiality where plaintiff disclosed material, non-public information to government regarding drug, but in following six years, government continued to approve and expanded authorized uses of drug and DOJ declined to intervene or take other action).

C. Relator Has Not Alleged Scienter.

To survive a motion to dismiss, relators also must allege facts establishing that the defendant "knowingly" presented a false or fraudulent claim for payment. 31 U.S.C. § 3729(a)(1)(A); *see Gonzalez v. Planned Parenthood of L.A.*, 759 F.3d 1112, 1115 (9th Cir. 2014) (explaining that knowing falsity "means a lie").

Government knowledge and approval "of the particulars of a claim for payment before that claim is presented" negates scienter because a party cannot knowingly lie to someone if they already know the truth. *United States ex rel. Costner v. United States*, 317 F.3d 883, 887 (8th Cir. 2003); *see also United States v. Bollinger Shipyards, Inc.*, 2013 WL 393037, at *9 (E.D. La. 2013) (dismissing claim noting "[t]he government's knowledge of the alleged false claim is relevant to whether the defendant 'knowingly' submitted a false claim").

Here, the government was aware of ESI's dispensing practices via public disclosures and its contractually required access to data. As discussed above, *supra* Section II.B, DHA was aware of and approved of ESI's dispensing practices by renewing its contract twice while having full knowledge of the dispensing practices and claims data. Yet, DHA continued to pay ESI. That negates scienter. *See Gonzalez*, 759 F.3d at 1115-16 (affirming dismissal for lack of scienter where the government communicated with defendant, was aware of defendant's conduct, did not pursue money owed by defendant, and never suggested defendant made

knowingly false claims). That the government had full knowledge of ESI's practices both underscores the reasonableness of ESI's conduct and negates scienter as a matter of law.

CONCLUSION

For these reasons, the district court's order dismissing the Complaint should be affirmed.

Dated: January 16, 2024

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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